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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNIEV DOCUMENT | |
| 09/775,743 | 02/02/2001 | Lioudmila Tchistiakova | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| | | Lioddinia i chistiakova | 082181-36154 | 9394 |
| | 590 06/20/2002 | | | |
| GIBBONS, D | EL DEO, DOLAN, | | - | |
| MATARKE | II PLAZA | · Locinone | EXAMINER | |
| NEWARK, NJ | 07102-5497 | | CHERNYSHEV, OLGA N | |
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| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | 11 |
| | | | DATE MAILED: 06/20/2002 | () |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| j. | • | Application No. | Applicant(s) |
|--------------------------|--|--|--|
| Office Action Summary | | 09/775,743 | TCHISTIAKOVA ET AL. |
| | amee Addon Summary | Examiner | Art Unit |
| | The MAILING DATE of this age | Olga N. Chernyshev | |
| Period fe | • • | appears on the cover sheet wi | th the correspondence address |
| after - If the - If NO | ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION nsions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory perior to reply within the set or extended period for reply will, by state eply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b). | 1.136(a). In no event, however, may a re | ply be timely filed (30) days will be considered timely |
| 1) | Responsive to communication(s) filed on | | |
| 2a)[☐ | This setting the second | his action is non-final. | |
| 3) | Since this application is in condition to it. | | |
| Dispositio | closed in accordance with the practice under on of Claims | Ex parte Quayle, 1935 C.D. | ers, prosecution as to the merits is 11, 453 O.G. 213 |
| | Claim(s) <u>25-41</u> is/are pending in the applicati | . | |
| 4 | a) Of the above claim(s) is/are withdra | Wn from considered: | |
| 5) 🗌 (| Claim(s) is/are allowed. | with forth consideration. | |
| | Claim(s) is/are rejected. | | |
| 7) 🗌 C | Claim(s) is/are objected to. | | |
| 8)⊠ C Applicatio | laim(s) <u>25-41</u> are subject to restriction and/or n Papers | election requirement. | |
| | e specification is objected to by the Examine | | |
| 10)∐ Th | e drawing(s) filed on is/are: a) accep | ted or h)□ objects to the | _ |
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| | S since the line of the | IS All Langroyed by Late- | 2. See 37 CFR 1.85(a). |
| | | IV to this Ofc | proved by the Examiner. |
| / | ected to by the Exa | miner. | |
| riority und | er 35 U.S.C. §§ 119 and 120 | | |
| ردا د ⊐رد | knowledgment is made of a claim for foreign | priority under 35 U.S.C. § 11 | 9(a)-(d) or (f) |
| . – | Am aguille of thought | | - (~) (4) Oi (i). |
| ا.ل ع ٦ | Certified copies of the priority documents | have been received. | |
| ۷.۲ | Described copies of the priority documents: | have been recoived in A | ation No. |
| * See t | application from the International Bure the attached detailed Office action for a list of | / documents have been rece au (PCT Rule 17.2(a)). | ived in this National Stage |
| . — | a claim for domestic r | riority under 25 U.O.O. a | |
| a) [] | The translation of the foreign language provison owledgment is made of a claim for domestic or | Signal application bases | θ (e) (to a provisional application). |
| 15)∐ Ackna achment(s) | owledgment is made of a claim for domestic p | priority under 35 U.S.C. 88 12 | eceived. 20 and/or 121 |
| | eferences Cited (PTO-892) | 5. 33 12 | GIIU/UL 121. |
| Notice of D | eleterices Cited (PTO_200) | | |
| INOTICE Of D | raftsperson's Patent Drawing Review (PTO-948) Disclosure Statement(s) (PTO-1449) Paper No(s) | 4) 🔲 Interview Summa | ry (PTO-413) Paper No(s) ! Patent Application (PTO-152) |

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 25-26, 32-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:1, classified in class 530, subclass 326, for example.
 - II. Claims 25, 27, 32-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 326, for example.
 - III. Claims 25, 28, 32-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:3, classified in class 530, subclass 326, for example.
 - IV. Claims 25, 29, 32-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:4, classified in class 530, subclass 326, for example.
 - V. Claims 25, 30, 32-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:5, classified in class 530, subclass 326, for example.
 - VI. Claims 25, 31-36 in so far as they are drawn to a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:7, classified in class 530, subclass 326, for example.

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- VII. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:1, classified in class 514, subclass 2, for example.
- VIII. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:2, classified in class 514, subclass 2, for example.
- IX. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:3, classified in class 514, subclass 2, for example.
- X. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:4, classified in class 514, subclass 2, for example.
- XI. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:5, classified in class 514, subclass 2, for example.
- XII. Claim 37, in so far as it is drawn to a method of treating a disease by administrating a pharmaceutical compound comprising amino acid sequence of SEQ ID NO:7, classified in class 514, subclass 2, for example.
- XIII. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:1, vector and a host cell classified in class 435, subclass 69.1, for example.

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- XIV. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:2, vector and a host cell classified in class 435, subclass 69.1, for example.
- XV. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:3, vector and a host cell classified in class 435, subclass 69.1, for example.
- XVI. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:4, vector and a host cell classified in class 435, subclass 69.1, for example.
- XVII. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:5, vector and a host cell classified in class 435, subclass 69.1, for example.
- XVIII. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:7, vector and a host cell classified in class 435, subclass 69.1, for example.
- XIX. Claims 38-41, in so far as it is drawn to a nucleic acid molecule encoding a polypeptide of SEQ ID NO:8, vector and a host cell classified in class 435, subclass 69.1, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

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instant case the different inventions are directed to compounds that have different chemical structure and are not required one for the other and, therefore are patentably distinct.

- 3. Inventions (I-VI) and (XIII-XIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups (XIII-XIX) and polypeptides of Groups (I-VI) are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.
- 4. Inventions (VII-XII) and (XIII-XIX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the DNA of Groups (XIII-XIX) are not required for the methods of Groups (VII-XII).
- 5. Inventions XIII, XIV, XV, XVI, XVII, XVIII and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to compounds that have

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different chemical structure and are not required one for the other and, therefore are patentably distinct.

- 6. Inventions VII, VIII, IX, XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods involving using compounds that have different chemical structure and are not required one for the other and, therefore are patentably distinct.
- 7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Olga N. Chernyshev, Ph.D. June 12, 2002

JOHN ULM PRIMARY EXAMINER GROUP 1800